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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,199	01/16/2002	Adnan Shennib	ISM/006CNT	9072

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EXAMINER

HARVEY, DIONNE

ART UNIT

PAPER NUMBER

2643

2

DATE MAILED: 04/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/052,199

Applicant(s)
Shennib

Examiner
Dionne Harvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the medially tapered lateral section of claim 3, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35

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U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1,3,4,6-9,11,14,17-19,22-24,29-32,34-36 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Brimhall (US 6,359,993).

Claim 1, Brimhall teaches a hearing device adapted for extended wear (column 5, lines 60-63) entirely within the ear canal, comprising: a core assembly(10) including a lateral section(14) having a microphone(24) and battery(136), and a receiver section(16) having a receiver(32); a sealing retainer(38) positioned over the receiver section for conforming to the walls at the bony region of the ear canal and for acoustically sealing against feedback within the canal; a lateral section being of *generally* oval cross sectional perimeter, as broadly claimed, and of generally but limited to cylindrical and elongated shape along its longitudinal axis, the lateral section being adapted for partial lateral suspension in the ear canal (see figure 5) without occlusion when the device is inserted within the canal.

Claim 3, Brimhall teaches that the lateral section is medially tapered.

Claim 4, Brimhall teaches that the lateral section is dimensioned for non-occlusion and minimal or no contact with the ear canal.

Claim 6, Brimhall teaches that the core comprises a moisture-proof encapsulation (28,42) which is at least partially exposed directly to the environment of the ear canal.

Claim 7, Brimhall teaches that the receiver section is flexibly connected to the lateral section, see elements 26 and 52, also see figure 2, thus allowing movement.

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Claim 8, Brimhall teaches a debris guard (30) for protecting the receiver.

Claim 9, Brimhall teaches an air vent(88).

Claim 11 Brimhall teaches, programming means (22) for adjustment of parameters.

Claim 14, Brimhall teaches that the sealing retainer has an oval cross-sectional perimeter.

Claim 17, Brimhall teaches that the sealing retainer is composed of conformable material.

Claim 18, Brimhall teaches that the sealing retainer is composed of silicone or polyurethane material, see col. 5, line 67..

Claim 19, Brimhall teaches that the sealing retainer forms an air gap (84) relative to the receiver, col. 5, lines 18-22..

Claim 22, in column 7, lines 38-40 and Brimhall teaches an assortment of different sizes and shapes of said sealing retainer.

Claim 23, Brimhall teaches a strand(80) to aid in placement or removal of the device.

Claim 24, Brimhall teaches a cross sectional perimeter having a long diameter to short diameter ration of approximately 1.4, see figure 6.

Regarding Claims 29 and 38, In the Preamble, no patentable weight has been given to the hearing aid's intended use to be a single-use disposable device. In figure 6, Brimhall teaches a hearing device adapted to be positioned entirely within an ear canal for extended wear comprising: a core assembly(110) including: a lateral section (118) containing a microphone(124) and battery(136), since the battery is not located on the surface of the face plate of the device and is instead located within the hearing aid housing along with the device's sound processing

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electronics. Since Brimhall does not specifically teach that the faceplate is removable so as to allow access to internal components, it appears that the battery is non-removably integrated within the lateral section, having a generally oval cross sectional perimeter and of generally but limited to cylindrical and elongated shape along its longitudinal axis, and a receiver section(16) containing a receiver(32), the receiver section coupled to said lateral section (26) and medially positioned in the bony region of the ear canal; a sealing retainer (38) positioned over the receiver section and conforming to the walls of the ear canal at the bony region and for at least partially laterally suspending the lateral section in the ear canal (see figure 5); said lateral section being non-occluding with minimal or no contact with the walls of the ear canal.

Claim 30, Brimhall teaches that the receiver section is flexibly connected to the lateral section, via elements 26 and 52 in figure 2, thus allowing movement.

Claim 31, Brimhall teaches that the sealing retainer is composed of conformable material.

Claim 32, Brimhall teaches that the sealing retainer forms an air gap (84) relative to the receiver, see col. 5, lines 18-22.

Claim 34, in column 7, lines 38-40 and Brimhall teaches an assortment of different sizes and shapes of said sealing retainer.

Claim 35, Brimhall teaches that the sealing retainer is composed of silicone or polyurethane material, see col. 5, line 67.

Claim 36, Brimhall teaches that the device may be worn for an extended period of time without daily insertion or removal, in column 5, lines 60-63, Brimhall teaches that the device is

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constructed specifically with materials which minimize the chances of infection from when the device is worn for extended periods of time, thereby negating the need to remove the device daily.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall (US 6,359,993) in view of Devoe (US 5,572,594).

Claim 5, Brimhall does not specifically teach a stabilizer, between the outer surface of the lateral section and the ear canal, for positioning the lateral section of the device within the ear canal. In figure 2B and 3B, Devoe teaches a stabilizer(18), formed with the housing of an ear canal device, located between the outer surface of the device and the ear canal. It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the teachings of Brimhall and Devoe, providing an outer stabilizing element for the lateral section of Brimhall, for the purpose of holding the lateral section of the device within the ear of the user.

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5. Claims 2 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall (US 6,359,993) in view of Aceti (US 6,473,511).

Claims 2 and 26, Brimhall does not specifically teach that the battery assembly is rechargeable. Aceti teaches a battery assembly for a disposable hearing aid which is rechargeable via an external power source. It would have obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Brimhall and Aceti for the purpose of obviating the need to replace batteries in increasingly smaller devices.

6. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall (US 6,359,993) in view of Leenen (US 6,229,900).

Regarding claims 12 and 13, Brimhall does not specifically teach that the hearing device includes remote control means operative using at least one of sound, ultrasound, magnetic, electromagnetic, radio frequency and infrared signals, for controlling at least one of the parameters of the hearing device. However, Lenin teaches a hearing device which uses a remote control(14) for controlling parameters of the hearing device(16,18) wherein the remote control (14) uses infrared, ultrasonic sound or radio signals (column 4, lines 20-25). Therefore, it would have been obvious for one of ordinary skill in the art at the time of the invention to combine the teachings of Brimhall and Lenin, implementing a remote control device for use with the hearing device, for the purpose of permitting the user to change different parameters of the hearing device so as to adapt to various hearing situations.

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7. Claims 15,16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall (US 6,359,993) in view of Shennib (US 5,701,348).

Regarding claims 15 and 16, Brimhall does not teach that the sealing retainer is composed of compressible material. Shennib teaches that the sealing retainer(43) for the receiver may be form of compressible material such as silicone or foam. It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the teachings of Brimhall and Shennib, forming the receiver sealing member from inexpensive compressible materials, so as to allow for cleaning of the member or easy disposal and replacement.

Regarding claim 20, Shennib teaches that the sealing member is removable and disposable, see col. 9, lines 64-65.

8. Claims 25,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shennib (US 5,701,348) in view of Brimhall (US 6,359,993)

Claim 25, in figure 3, Shennib teaches a battery assembly for connection to a core(10) assembly of an extended wear canal hearing device, comprising: an outer enclosure(15) adapted for direct exposure to the environment of the ear canal, also facilitating battery replacement for the user, said battery assembly adapted to be combine with a microphone section (14) of the core (10) to form a lateral section(12) of generally oval cross-sectional perimeter (figure 3) and generally cylindrical and elongated shape(figure 4) along it's longitudinal axis. Shennib does not

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teach that the lateral section is adapted for at least partial lateral suspension in the ear canal without occlusion thereof.

Brimhall teaches an articulated hearing aid having a core assembly. The core assembly including a lateral section(14) having at least partial lateral suspension in the ear canal (figure 5). It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the teachings of Shennib and Brimhall, thereby providing the lateral section of Shennib with an at least partially suspended construction for the purpose of reducing the degree of pressure to be exerted on the wall of the ear canal.

Claim 27, Brimhall teaches that the lateral section is medially tapered.

Claim 28, Brimhall teaches that the lateral section is dimensioned for non-occlusion and minimal or no contact with the ear canal.

9. Claims 10,21,33 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall (US 6,359,993).

Claim 10, Brimhall does not specifically teach that the microphone includes an amplifier for processing acoustic signals. However, the Examiner that the Official Notice that the use of an amplifier integral with a microphone is well known in the art and would have been obvious for the purpose of amplifying the captured sound signal for conversion into a sound pressure signal which may be perceived by the eardrum.

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Claim 21 and 33, Brimhall fails to specifically teach that the sealing retainer comprises medication material including anti-bacterial and anti-microbial agents. However, the Examiner takes Official Notice that it is well known in the art and would be obvious to one of ordinary skill in the art at the time of the invention to use such materials in an effort to increase the comfort of using such devices for placement in easily irritated and/or sensitive body cavities.

Claim 37, Brimhall does not specifically teach that the user may wear the device for extended period of at least one week. However, Brimhall does not restrict to any specific length of time. As such, it would be fair to interpret the hearing aid of Brimhall as capable of being worn for periods up to and beyond at least one week to negate the periodic removal of the device by the user.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne Harvey whose telephone number is (703) 305-1111. The examiner can normally be reached on Monday through Friday from 8:30am to 6:00pm.

Any responses to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington, DC 20231

or faxed to:

(703) 308-6306, for formal communications for entry

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Or:

(703) 308-6296, for informal or draft communications, please label "PROPOSED" or "DRAFT".

Hand delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington, VA., Sixth Floor(Receptionist)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Kuntz, can be reached at (703) 305-4708.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne Harvey whose telephone number is (703) 305-1111.

D.H.

April 14, 2003


SINH TRAN
PRIMARY EXAMINER